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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,662	11/30/2000	Mark A. Hayes	31737PCTUSA	6662

7590 04/02/2004

Pitney, Hardin, Kipp & Szuch LLP  
685 Third Ave  
New York, NY 10017-4204

EXAMINER
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OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/701,662	<b>Applicant(s)</b> HAYES ET AL.	
	<b>Examiner</b> Kaj Olsen	<b>Art Unit</b> 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Farrell (USP 4,323,439). O'Farrell is being cited and relied on for the first time with this office action. This reference was brought to the examiner's attention since the previous office action.

3. O'Farrell discloses a method for controlling the movement of a specific sample component in a fluid sample comprising a pathway 100 that would appear to read on a "constrained fluid pathway" giving the claim language its broadest reasonable interpretation. O'Farrell teaches introducing a fluid sample to the fluid pathway, providing an electrode (130 or 132) mounted at the inlet of the fluid pathway with the electrode being entirely external of the fluid pathway (fig. 2). O'Farrell teaches applying a voltage to the electrode to create a voltage gradient with the pathway to promote electrophoretic migration while adjusting the flow rate of the fluid to be equal and opposite to the electrophoretic migration such that sample movement ceases. See col. 3, lines 18-36 and col. 6, lines 1-8.

4. The pathway 100 would read on a capillary channel giving the claim language its broadest reasonable interpretation (see col. 15, lines 61-67). However, see the alternative rejection below.

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5. With respect to the use of pressure, see paragraph bridging col. 6 and 7.
6. With respect to the apparatus claims (those limitations not discussed above), O'Farrell also teaches a means for delivering fluid sample into the constrained fluid pathway (col. 6, lines 60-67), and a means for adjusting the voltage on the electrode so that the movement of said sample ceases (col. 5, lines 14-27).
7. With respect to the buffer reservoir, see col. 15, lines 61-67.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. Claims 1-5, 8, 10, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blanchard et al (USP 5,151,164) with or without the further teaching of O'Farrell. Blanchard is being cited and relied on for the first time with this office action. This reference was brought to the examiner's attention since the previous office action.
10. Blanchard discloses a method for controlling the movement of a specific sample component in a fluid sample. Said method comprises providing a constrained fluid pathway (i.e. a capillary), introducing sample into the inlet of the constrained fluid pathway (col. 4, lines 40-54), and providing an electrode mounted at the inlet that is entirely external to the fluid pathway (see fig. 5A and 5B). Blanchard further discloses applying voltage to the electrodes to promote electrophoretic migration of the sample (col. 4, lines 47-58) and adjusting the flow rate via electroosmosis of the fluid to be opposite to the flow by electrophoretic migration (col. 3, lines 21-28 and Table 1. Although Blanchard does not explicitly disclose making this flow rate be

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equal to the electrophoretic flow rate, Blanchard recognized that the degree of control over the opposite flow rate depends on the degree of resolution desired (col. 5, lines 28-31). Hence, utilizing an equal and opposite flow rate would have been within the purview of one possessing ordinary skill in the art when said equal and opposite provides the desired resolution power.

11. Alternatively, O'Farrell already identified that equal and opposite flow is desired when one wishes to purify a given electrophoretic sample (see rejection above). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of O'Farrell for the method of Blanchard when one desires to purify various electrophoretic samples.

12. With respect to the capillary dimensions, see Blanchard, col. 5, lines 33-54.

13. With respect to the apparatus claims (those limitations not covered above), varying the voltage applied for electrophoresis to arrive at the desired electrophoretic flow requires only routine skill in the art. Alternatively, O'Farrell already rendered obvious the varying of the voltage to arrive at the desired flow conditions (col. 5, lines 14-27).

14. With respect to the use of buffer reservoir, see Blanchard, col. 5, lines 63-68.

15. Claims 4 and 14 (and claims 3 and 10 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Farrell in view of Blanchard.

16. O'Farrell set forth all the limitations of the claim, but did not explicitly recite the use of the claimed diameters. Blanchard set forth that capillaries with said dimensions are known in the art (col. 5, lines 33-54). Smaller capillaries improve the resolving power of the electrophoresis and are used when the amount of available sample is low. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of

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Blanchard for the method and apparatus of O'Farrell in order to improve the resolving power of the device and allow for small amounts of sample to be purified by the device.

17. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Farrell or Blanchard (with or without O'Farrell) in view of Manz (J. Micromech. Microeng. 4, 1994, pp. 257-265).

18. The references set forth all the limitations of claims 7 and 9, but did not explicitly recite the use of a microchip. Manz teaches in an alternate electrophoretic device that both capillaries and microchips are known means in the art for performing electrophoretic experiments (compare fig. 2 and 3 with 8). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Manz for the method and device of O'Farrell or Blanchard (with or without O'Farrell) because the substitution of one known means for sample analysis for another requires only routine skill in the art.

#### ***Response to Amendment***

19. Applicant amended the claims in view of indicated allowable subject matter. However as mentioned above, prior art (O'Farrell and Blanchard) has come to the examiner's attention since the previous office action and the previous indication of the allowability of the subject matter of claim 1 is hereby withdrawn.

#### ***Allowable Subject Matter***

20. Claims 15-17 are allowed.

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21. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not disclose nor render obvious all the limitations of claim 15 with particular attention to the specified means for adjusting the voltage in conjunction with the combination of injection and separation pathways with the second electrode being mounted at the inlet of the separation pathway.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj Olsen Ph.D.  
Primary Examiner  
AU 1753  
March 30, 2004